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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,977	07/14/2003	Brian L. Bates	PA-5335-RFB	5904

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EXAMINER	
SWEET, THOMAS	
ART UNIT	PAPER NUMBER
3738	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/618,977	BATES ET AL.	
	Examiner	Art Unit	
	Thomas J. Sweet	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/24/2006 02/12/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of species B, fig. 8 new method claims 35-48 in the reply filed on 02/01/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

"Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b).** Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action."

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

Claim 47 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

the inventor(s), at the time the application was filed, had possession of the claimed invention. Paragraph 100 does not support "up to" 20 minutes, it merely give an example of 20 minutes and state short times which does not reasonable establish 20 minutes as an upper limit.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35, 37-40, 42 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al (WO-00/45744). Yang et al discloses a method (balloon angioplasty, fig 5) of delivering a lipophilic bioactive material (Taxol- pg 5,line 12, i.e. paclitaxel) to an interior wall of a body vessel from an implantable medical device (a balloon, pg 12-13, lines 5-10) having an expandable balloon (pg 12, line 9) with the lipophilic bioactive material (Taxol- pg 5,line 12, i.e. paclitaxel) on an outer surface of the balloon (pg 12, lines 17-18), the method comprising the steps of: inserting the balloon into a body vessel (fig. 4), the balloon being free of (none disclosed): a coating atop the bioactive material, a time-release layer, a containment material and a containment layer (abs);

advancing the balloon within the body vessel to a treatment site within the body vessel (fig. 4);

inflating the balloon at the treatment site to contact the bioactive material with an inner wall of the body vessel (fig. 5);

maintaining the bioactive material on the outer surface of the inflated balloon in contact with the inner wall of the body vessel while the balloon is inflated (as shown);

deflating the balloon after contacting the bioactive material with the inner wall of the body vessel; and

removing the deflated balloon from the body vessel (the balloon inherently needs to be deflated and removed to restore flow).

With regard to claim 38, wherein the bioactive material further comprises a diagnostic agent (pg 9, lines 17-20, combination with radiopaque agents).

With regard to claims 39 and 40, angioplasty (pg 1, line 11) is on the coronary artery.

With regard to claim 42, the method is performed without- implanting a stent within the body vessel (pg 12, lines 8-9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 36, 43, and 47 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yang et al in view of either Trauthen et al. (US 6,491,619), Consigny (US 6,203,487), Zoldhelyi et al. (US 6,214,333) Ezrin et al. (US 6,706,892) or Carney (US 6,867,190). Yang et al discloses a method as discussed above. However, Yang et al remains silent as to any inflation time but angioplasty is inherently preformed using cycles of short inflation times up to about one minute because the inflation stops life giving flow to the heart. Trauthen et al., Consigny, Zoldhelyi et al., Ezrin et al. and

Carney evidence this. Each of which performs angioplasty with a minute or less inflation time over repeated intervals. If this is not considered inherent, it would have been obvious to one of ordinary skill in the art at the time the invention was made to inflate the angioplasty balloon of Yang et al in inflation times up to about one minute as taught by Trauthen et al., Consigny, Zoldhelyi et al., Ezrin et al. and/or Carney in order not to stop blood flow to the heart for extended periods.

With regard to claim 43, Yang et al remains silent as to the material of the balloon catheter, specifically a polyamide, polypropylene, polyether block amide or polyethylene. It is well known in the art of balloon catheters to use a polyamide, polypropylene, polyether block amide and polyethylene for the balloon membrane. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize polyamide, polypropylene, polyether block amide or polyethylene as the balloon catheter member either inherently or as mere substitution of one functionally equivalent balloon material for another within the art of balloon catheters.

With regard to claim 47, Yang et al remains silent as to maintained in contact with the inner wall of the body vessel for up to about 20 minutes. Even one inflation of the balloon for up to one minute is from 0-20 minutes meeting the claim. Each of the references (Trauthen et al., Consigny, Zoldhelyi et al., Ezrin et al. and Carney) demonstrates repeated inflations of less than about 20 minutes demonstrating the inherent or obviousness of the limitation.

Claims 41, 45 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al in view of Barry et al. (US 2003/0059454/provisional 60/324095). Yang et al

discloses a method as discussed above. However, Yang et al remains silent as to any dosing levels including about 5-500 micrograms. Barry et al teaches another method of delivering a lipophilic bioactive material (paclitaxel) to an interior wall of a body vessel from an implantable medical device (fig. 1) in the range of about 5 to about 500 micrograms (50-345) for the purpose preventing restenosis in a compatible range. The remainder of the range is obvious, since this can be determined by experimentation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to dose the paclitaxel coating of Yang et al in the range of about 5 to about 500 micrograms in order to compatibly prevent restenosis.

With regard to claim 48, Yang et al remains silent as to any dosing levels including a total of about 0.2 to about 20 micrograms of paclitaxel or a paclitaxel derivative per mm2 of the outer surface of the expandable balloon. Barry et al teaches from about 0.2 to about 20 micrograms (.6-4, fig. 1). As before the remained of the range is obvious, since this can be determined by experimentation. As modified above the claim is met.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al in view of Barry et al as applied to claims 41 and 48 above and in further view of either Trauthen et al. (US 6,491,619), Consigny (US 6,203,487), Zoldhelyi et al. (US 6,214,333) Ezrin et al. (US 6,706,892) or Carney (US 6,867,190). Yang et al as modified remains silent as to any inflation time but angioplasty is inherently preformed using cycles of short inflation times up to about one minute because the inflation stops life giving flow to the heart. Additionally, Yang et al remains silent as to maintained in contact with the inner wall of the body vessel for up to about 20 minutes. Trauthen et al., Consigny, Zoldhelyi et al., Ezrin et al. and Carney evidence this. Each of which performs angioplasty with a minute or less inflation time over repeated intervals. If this

is not considered inherent, it would have been obvious to one of ordinary skill in the art at the time the invention was made to inflate the angioplasty balloon of Yang et al in inflation times up to about one minute as taught by Trauthen et al., Consigny, Zoldhelyi et al., Ezrin et al. and/or Carney in order not to stop blood flow to the heart for extended periods. Even one inflation of the balloon for up to one minute is from 0-20 minutes meeting the claim. Each of the references (Trauthen et al., Consigny, Zoldhelyi et al., Ezrin et al. and Carney) demonstrates repeated inflations of less than about 20 minutes demonstrating the inherent or obviousness of the limitation.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kunz et al. (US 6,491,938), Hunter et al. (US 6,544,544), Hunter, William L. (US 6,515,016) and Griffin et al. (US 2002/0193828).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 5:45am - 4:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas J Sweet
Examiner
AU 3738